JUN 0 3 2002

K 014040

Attachment 17
510(k) Summary for the
Family of Altus Medical Modified CoolGlide Aesthetic Lasers

I. General Information

Submitter:	Altus Medical, Inc. 821 Cowan Road Burlingame, CA 94010
Contact Person:	Kathy Maynor
Summary Preparation Date:	December 1, 2001

II. Names

Device Names:	Family of Altus Medical Modified CoolGlide Aesthetic Lasers
Primary Classification Name:	Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Altus Medical Aesthetic Nd:YAG Laser (K991798, K991234 and K003202);
- VeinLase, manufactured by HGM (K981952);
- EpiLight PhotoDerm HR, manufactured by ESC Medical Systems (K991935 and K980537);
- LightSheer Pulsed Diode Array Laser System, manufactured by Star/Coherent Medical (K982940);
- Lyra and Orion/SL/Lyra Series Laser Systems and SmartScan, manufactured by Laserscope (K990718, K990903, K941841, K933880, K003147 and K003765); and
- Candela Long Pulse Nd:YAG Laser System, manufactured by Candela (K010104).

IV. Product Description

Family of Altus Medical Modified CoolGlide Aesthetic Lasers are comprised of the following main components:

- a laser system console (including software and control electronics);
- a control and display panel;
- a permanently attached fiberoptic-coupled handpiece;
- a skin cooling device integrated into the handpiece;
- a footswitch (or finger-operated exposure switch (handswitch) option integrated into the handpiece)
- a remote interlock connector (disables laser when treatment room door is opened).

V. Indications for Use

The family of Modified Altus Medical CoolGlide Aesthetic Lasers are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

1064nm:

Dermatology:
The Altus Medical Aesthetic CoolGlide laser systems are intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos(significant reduction in the intensity of black and/or blue/black tattoos) and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The CoolGlide lasers are also indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

The lasers are also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The CoolGlide lasers are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The intended use of the integral cooling system in the Altus handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Surgical Applications::
The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostatis of soft tissue in the performance of surgical applications in endosopy/laproscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

Indications for use (532nm):

For coagulation and hemostasis of vascular and cutaneous lesions in dermatology including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

VI. Rationale for Substantial Equivalence

The family of Altus Medical Modified CoolGlide Aesthetic Lasers share the same general indications for use, and therefore is substantially equivalent to the currently marketed Altus Medical Aesthetic Nd:YAG Laser (K991798, K991234 and K003202), the VeinLase, manufactured by HGM (K981952), the EpiLight PhotoDerm HR, manufactured by ESC Medical Systems (K991935 and K980537), the LightSheer Pulsed Diode Array Laser System, manufactured by Star/Coherent Medical (K982940), the Lyra and Orion/SL/Lyra Series Laser Systems and SmartScan, manufactured by Laserscope (K990718, K990903, K941841, K933880, K003147 and K003765), and the Candela Long Pulse Nd:YAG Laser System manufactured by Candela (K010104).

VII. Safety and Effectiveness Information

The new **indications for use** in dermatology, endoscopic/laproscopic general surgery, gastroenterology, general surgery, gynecology, otorhinolaryngology, neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary.thoracic surgery, and urology are based upon the indications for use for predicate laser systems.

Technologically, the modified CoolGlide family of aesthetic lasers is identical to the previous predicate CoolGlide family (K003202). Therefore the risks and benefits for the modified CoolGlide laser family are comparable to the predicate devices.

We therefore believe that there are no questions of safety or effectiveness raised by the introduction of this device.

VIII. Conclusion

The family of Altus Medical Modified CoolGlide Aesthetic Lasers were found to be substantially equivalent to the currently marketed Altus Medical Aesthetic Nd:YAG Laser (K991798, K991234 and K003202), the VeinLase, manufactured by HGM (K981952), the EpiLight PhotoDerm HR, manufactured by ESC Medical Systems (K991935 and K980537), the LightSheer Pulsed Diode Array Laser System, manufactured by Star/Coherent Medical (K982940), the Lyra and Orion/SL/Lyra Series Laser Systems and SmartScan, manufactured by Laserscope (K990718, K990903, K941841, K933880, K003147 and K003765) and the Candela Long Pulse Nd:YAG Laser System (K010104). The family of Altus Medical Modified CoolGlide Aesthetic Lasers share similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 3 2002

Ms. Kathy Maynor
Vice President of Regulatory/Quality
Altus Medical, Inc.
821 Cowan Road
Burlingame, CA 94010

Re: K014040
Trade/Device Name: Family of Altus Medical Modified CoolGlide Aesthetic Lasers
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 6, 2002
Received: March 8, 2002

Dear Ms. Maynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K014040

Device Name: **Family of Altus Medical Modified CoolGlide Aesthetic Lasers**

Indications For Use:

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1064nm:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014040

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

The Modified CoolGlide lasers are also indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014040

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96

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(Division Sign-Off)
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